REMARKS

Rejection Under 35 USC §101

Claims 1 and 5-8 are rejected under 35 U.S.C. §101 as lacking a credible, substantial and specific utility. This rejection is respectfully traversed.

To properly reject a claimed invention under 35 U.S.C. §101, the Patent Office must (A) make a *prima facie* showing that the claimed invention lacks utility, and (B) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing (M.P.E.P. §2107.02 IV). Applicant submits that the Examiner has not made a *prima facie* showing that the claimed invention lacks utility.

Specific Utility

Regardless of the category of invention that is claimed, an Applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. §101 and 35 U.S.C. §112; additional statements of utility, even if not credible, do not render the claimed invention lacking in utility (M.P.E.P. 2107.02).

In the present disclosure, Applicant asserts a role for the present invention (nucleic acid molecule of SEQ ID NO: 1) in regulating the development and growth of myeloid leukemia cells (page 66, lines 3-15). The present specification teaches that terminal differentiation of myelomonocytic precursor cells results in down regulation of Evi27 expression. However, proviral insertions at Evi27 result in constitutive expression of the Evi27 receptor. Binding of ligands to the Evi27 receptor triggers the release of TNF-α and IL-1β by the leukemic cells. The secreted TNF-α and IL-1β would in turn provoke production of multilinage hematopoietic growth factors, adhesion molecules, and inflammatory cytokines by stromal cells. These stromal cell-derived factors then support the growth and survival of the leukemia cells. This model of leukemia cell growth is consistent with and supported by the fact that B160 leukemia cells are absolutely dependent on stromal feeder cell layer for growth and survival.

In view of the above disclosure, one of ordinary skill in the art would readily recognize that *Evi27*-encoded receptor mediates proinflammatory cytokine secretion and plays an important role in the growth of myeloid leukemia cells. Accordingly, one of ordinary skill in the art would reasonably conclude that modulating the

expression of *Evi27*-encoded receptor can be exploited to regulate proinflammatory cytokine secretion and growth of myeloid leukemia cells. More specifically, inhibition of proinflammatory cytokine secretion and myeloid leukemia cell growth could be accomplished by inhibiting the expression and function of Evi27 receptor.

It is well-known in the art that gene expression and/or function can be inhibited by anti-sense oligonucleotides or antibody. In the instant case, one of ordinary skill in the art would readily recognize that Evi27 gene expression could be inhibited by anti-sense Evi27 oligonucleotides, and ligand binding to Evi27 receptor could be inhibited by antibody directed against the Evi27 receptor. But a person having ordinary skill in this art would need to know the gene sequence of Evi27 receptor before anti-sense Evi27 oligonucleotides can be generated. One also needs to know the DNA sequence for the Evi27 receptor to construct recombinant Evi27 receptor protein for the generation of anti-Evi27 antibodies. The requisite DNA sequence for the Evi27 receptor is provided by the instant invention (SEQ ID NO: 1).

In view of the above remarks, Applicant submits that there is a specific utility for the instant invention (SEQ ID NO: 1) in, *inter alia*, regulating proinflammatory cytokine secretion and myeloid

leukemia cell growth, and one of ordinary skill in the art could readily utilize the DNA sequence of the instant invention in standard conventional protocols to regulate myeloid leukemia cell growth *in vitro* or *in vivo*.

Substantial Utility

A substantial utility is a real world use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context of use are not substantial utilities (M.P.E.P. 2107.01). Applicant submits that the above asserted utility for SEQ ID NO: 1 is a substantial use that does not require further research to identify a real world context of use.

As discussed above, one of ordinary skill in the art would readily utilize SEQ ID NO: 1 to generate anti-sense Evi27 oligonucleotides or construct recombinant Evi27 receptor protein for the generation of anti-Evi27 antibodies. These oligonucleotides or antibodies can be readily employed in standard protocols to inhibit the expression and function of Evi27 receptor *in vitro* or *in vivo*, thereby inhibiting the growth of myeloid leukemia cells. Accordingly, Applicant respectfully submits that inhibiting the growth of myeloid

leukemia cells *in vitro* or *in vivo* is a substantial use of the instant invention.

Credibility of Asserted Utility

An Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101 (M.P.E.P. 2107.02). As discussed above, Applicant submits that the specification has provided a specific utility for the instant invention (SEQ ID NO: 1) in regulating proinflammatory cytokine secretion and myeloid leukemia cell growth. Applicant further submits that a person having ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention disclosed and discussed above.

To overcome the presumption of truth that an assertion of utility by the applicant enjoys, Patent Office personnel must establish that it is more likely than not that one of ordinary skill in the art would doubt or question the truth of the statement of utility (M.P.E.P. 2107.02). Applicant submits that the examiner has not addressed or raised any issue related to the model of regulating myeloid leukemia cell growth by Evi27 receptor protein as discussed above; nor does the Examiner provide any reason why one of

ordinary skill in the art would have doubt on such model and question the truth of the statement of utility. Applicant submits that the Examiner has failed to establish a *prima facie* case showing the claimed invention lacks utility. Accordingly, Applicant respectfully requests that the rejection of claims 1 and 5-8 under 35 U.S.C. §101 be withdrawn.

Rejection Under 35 USC §112, 2nd Paragraph

Claim 5 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection is moot because claim 5 has been canceled.

Rejection Under 35 USC §112, 1st Paragraph

Claim 5 is rejected under 35 U.S.C. §112, first paragraph, for failing to comply with written description requirement. The rejection is moot because claim 5 has been canceled.

Rejections Under 35 USC §102

Claim 5 is rejected under 35 USC §102(b) as anticipated by Copeland et al. The rejection is moot because claim 5 has been canceled.

This is intended to be a complete response to the Office Action mailed October 20, 2004. If any issues remain outstanding, the examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

Date: Jan 11, 2005

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